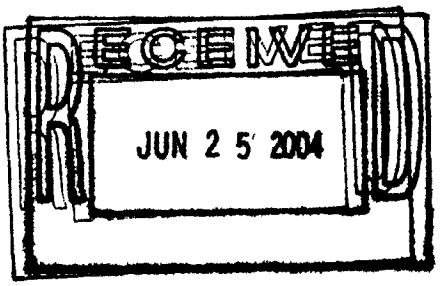

DATE: June 22, 2004

NOTE TO FDA Dockets Management Branch

DOCKET NO.: 2004N-0018

SUBJECT: Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application

PUB DATE: 6/10/04

The September 30, 1993, Executive Order 12866--Regulatory Planning and Review sets forth the Administration's principles and requirements for the Federal regulatory process. Under section 6(a)(3)(E) of the Executive Order, for "significant regulatory actions," Federal agencies must make certain information available to the public after publication of the regulatory action in the Federal Register.

Pursuant to the Executive Order, FDA has attached, for significant regulatory actions, in this docket the following information:

1) A copy of the draft regulatory action as submitted to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) for review including any materials or assessments, required by the Executive Order, that accompanied the draft, with substantive changes between the draft submitted to OIRA for review and the action subsequently announced, if any (see mark-ups, TAB A); and

2) Those changes in the regulatory action that were made at the suggestion or recommendation of OIRA, if any (see TAB B).

Amber MacKenzie
Regulatory Counsel
Regulations Policy and
Management Staff
(HF-26)

Attachment(s)

2004N-0018

REF 1